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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,741	11/30/2001	Mary M. Dyszlewski	1328 WO/US	2094

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EXAMINER

JONES, DAMERON

ART UNIT PAPER NUMBER

1616

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,741

Applicant(s)

DYSZLEWSKI ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____.

APPLICANT'S INVENTION

1. The instant invention is directed to methods of preparing compounds of formulae I and II as set forth in independent claims 1 and 15.

Note: Claims 1-28 are pending.

DOUBLE PATENTING REJECTIONS

2. ~~The nonstatutory double patenting rejection is based on a judicially created~~ doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3, 6-11, 13, 14, 23, 24, 27, and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-6, 12-15, and 17 of U.S. Patent No. 6,344,178. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims encompass those of the instant invention. In particular, the claims differ in that the patented claims do not require that a basic borate buffer be present.

4. Claims 1-3 and 6-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 8, 9, and 11-17 of U.S. Patent No. 6,359,119. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims encompass those of the instant invention. In particular, the claims differ in that the patented claims do not require that a basic borate buffer be present.

102 REJECTIONS

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 2, and 5-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Alberto et al (J. Am. Chem. Soc., 1998, 120, pp. 7987-7988).

Alberto et al (Reference #1) disclose the synthesis of $[^{99m}\text{Tc}(\text{OH})_2(\text{CO})_3]^+$ from $[^{99m}\text{TcO}_4]$ and the labeling of biomolecules (see entire document, especially, Scheme 1). In addition, Alberto et al disclose (1) that the presence of large amounts of tartrate and citrate did not seriously suppress the formation of $[^{99m}\text{Tc}(\text{OH})_2(\text{CO})_3]^+$. (2) A reducing agent such as $[\text{S}_2\text{O}_4]^{2-}$ may be used. (3) Proteins may be labeled with $[^{99m}\text{Tc}(\text{OH})_2(\text{CO})_3]^+$. (4) In Scheme 2, the ligand picolinamine-N,N-diacetic acid (PADA), and aminopolycarboxylic acid, is studied (see also, Figure 2). (5) It should be noted that imino-N,N-diacetic acid was also used (see pages 7987-7988).

Thus, both Alberto et al and the cited prior art disclose a method of preparing fac- $[\text{M}(\text{CO})_3(\text{OH})_2]^+$.

7. Claims 1, 2, 3, 5-19, 21-24, and 26-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Alberto et al (WO 98/48848).

Alberto et al (Reference #2) disclose a method of preparing facial metal tricarbonyl compounds and using them to label biologically active substrates. In addition, Alberto et al disclose (1) compounds having the formula of $[\text{M}(\text{OH})_2(\text{CO})_3]^+$ wherein M is Mn, ^{99m}Tc , ^{186}Re , or ^{188}Re . The compounds are generated by reacting a metal in the permethylate form with carbon monoxide and a reducing agent wherein the mixture is characterized in that the reducing agent which is soluble in water is not substantially decomposed by water. Also, a stabilizing agent may be present. (2) Various substrates such as amino acids, peptides, proteins, sugars, small receptor binding molecules and body cells may be labeled. (3) A kit for the preparation of the

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labeled complex is also disclose (see entire document, especially, abstract; page 2, lines 20-31; page 3, lines 20-28; page 4, lines 1-35; page 5, lines 4-35; page 6, lines 16-35; page 7, lines 16-25). (4) Examples are disclosed wherein of $[99mTc(OH)_2(CO)_3]^+$ complexes are generated under various conditions (Examples 1-6, pages 8-13).

Thus, both Alberto et al and the cited prior art disclose a method of preparing $[M(OH)_2(CO)_3]^+$

103 REJECTIONS

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3, 17, 19, 21-24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alberto et al (J. Am. Chem. Soc., 1998, 120, pp. 7887-7988).

Alberto et al (Reference #1, see discussion above) fail to disclose KBH_4 or a kit for the of $[M(OH)_2(CO)_3]^+$ complex.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Alberto et al and use KBH_4 as the reducing agent or generate a kit comprising the metal containing complex because (a) a skilled practitioner in the art would recognize that the replacement of $NaBH_4$ with KBH_4 is within the skill of a practitioner since the replacement of one element with another one

in the same chemical family and having the same/similar chemical properties would not drastically alter the overall properties of NaBH₄. (b) It would have been obvious to generate a kit because of the ever present need to have such kits readily available in hospitals, clinic, or other medical facilities.

10. Claims 1, 4, 15, 17, 20, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alberto et al (J. Am. Chem. Soc., 1998, 120, pp. 7887-7988).

Alberto et al (Reference #2, see discussion above) fail disclose an example wherein lactose is present in the mixture.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include lactose in the mixture because on page 4, lines 25-26, it is disclosed that sugars may be labeled with the complex disclosed in Reference #2. Thus, since lactose is a sugar, it would be obvious to replace one sugar with another sugar.

SPECIFICATION

11. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a 371 of Application No. PCT/US00/17813, filed 6/28/00." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Note: Applicant should also update the continuing data to include provisional application number 60/140,989.


COMMENTS/NOTES

12. The references listed on the PTO-892 and not cited in a rejection above were cited on PCT/US00/17813.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
Art Unit 1616

February 3, 2003